Repair of Thoracic and Thoracoabdominal Mycotic Aneurysms and Infected Aortic Grafts Using Allograft

Running Head: Cryopreserved Allograft in Aortic Repair

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Abstract

Background: Mycotic aneurysm of the thoracic or thoracoabdominal aorta and infection of thoracic or thoracoabdominal aortic grafts are challenging problems with high mortality. In-situ reconstruction with cryopreserved allograft(CPA) avoids placement of prosthetic material in an infected field and avoids suppressive antibiotics or autologous tissue coverage.

Methods: Fifty consecutive patients with infection of a thoracic or thoracoabdominal aortic graft or mycotic aneurysm underwent resection and replacement with CPA from 2006 to 2016. Intravenous antibiotics were continued postoperatively for 6 weeks. Long-term suppressive antibiotics were uncommonly used (8 patients). Follow up imaging occurred at 6, 18 and 42 months postoperatively. Initial follow up was 93% complete.

Results: Males comprised 64% of the cohort. The mean age was 63±14 years. The procedures performed included reoperations in 37, replacement of the aortic root, ascending aorta or transverse arch in 19, replacement of the descending or thoracoabdominal aorta in 27 and extensive replacement of the ascending, arch and descending or thoracoabdominal aorta in 4. Intraoperative cultures revealed most commonly staphylococcus 24%), enterococcus (12%), candida (6%) and gram negative rods (14%). Operative mortality was 8%, stroke 4%, paralysis 2%, hemodialysis 6%, and respiratory failure requiring tracheostomy 6%. Early reoperation for pseudoaneurysm of the CPA was necessary in 4 patients. One, two and five year survival was 84%, 76% and 64%, respectively.

Conclusions: Radical resection and in-situ reconstruction with CPA avoids placing prosthetic material in an infected field and provides good early and mid-term outcomes. However, early postoperative imaging is necessary given the risk of pseudoaneurysm formation.

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An infected thoracic aortic graft is an uncommon, but challenging reoperative problem. For patients who have undergone previous open repair of the thoracic aorta, the infection rate is 0.9 to 1.9% [1-4]. Mortality for reoperative repair is 25% to 75% [2,3]. Although the increased use of endovascular therapies for primarily descending thoracic aortic disease has reduced morbidity for the initial repair, these interventions are not without infectious complication. The infection rate of an endovascular graft is 0.2-0.5% [5-7].

Infection of the native thoracic or thoracoabdominal aorta is another uncommon surgical problem comprising 0.7% to 4.5% of all aortic aneurysms [8]. It has been suggested by Jaffer to treat these entities differently from infected aortic grafts by using operative visceral debranching and thoracic endograft techniques, as the reinfection risk for mycotic aneurysms is less than that of infected grafts [9]. In contrast to this strategy, we have approached primary aortic infections and infected aortic grafts similarly using radical open debridement and in-situ repair with cryopreserved allograft (CPA). The bulk of the surgical literature on mycotic aortic aneurysm regards the abdominal aortic and aorto-iliac location and mortality is 30-40% [9,10].

While prosthetic graft has a substantial risk for reinfection when placed in an infected field, CPA has demonstrated resistance to infection and has proven results treating prosthetic and native aortic valve endocarditis [8,12-16]. Operative results using CPA for native and prosthetic arterial infection still have significant morbidity and mortality in abdominal aortic and peripheral arterial applications, however CPA repair has durable and reinfection-free mid-term outcomes [17-21]. Vogt and colleagues described improved early and late survival using CPA with direct comparison to prosthetic graft in both thoracic and abdominal aortic application [22,23]. The 2016 American Heart Association Scientific Statement on

vascular graft infection, mycotic aneurysm and endovascular infection provides a Class IIa recommendation for the use of in-situ reconstruction using CPA for thoracic aortic graft infection [8].

This analysis represents the largest study of the use of CPA for in-situ reconstruction of the thoracic and thoracoabdominal aorta in the setting of mycotic aortic aneurysm or infection of a prosthetic aortic graft.

Patients and Methods

The Institutional Review Board of Indiana University approved the study. A retrospective review was performed of fifty consecutive patients who underwent reconstruction using cryopreserved allograft for an infected thoracic or thoracoabdominal aortic graft or a primary infection of the thoracic or thoracoabdominal aorta between January 1, 2006 and December 31, 2016. Patients with isolated aortic valve endocarditis (native or prosthetic), isolated infrarenal mycotic aneurysm or infected infrarenal graft without a proximal thoracoabdominal aneurysm who had repair with CPA were excluded from the study.

The diagnosis of an infected thoracic or thoracoabdominal aortic graft was made based on the presentation of a constellation of 1) symptoms including fever and sepsis, 2) abnormal laboratory studies including elevated C-reactive protein, sedimentation rate, procalcitonin, or white blood cell count, 3) positive blood cultures and/or positive cultures of other infectious foci and 4) radiographic studies showing pseudoaneurysm, abnormal fluid or air around a surgical graft or endograft. The diagnosis of a mycotic aneurysm includes 1, 2 and 3 above, and radiographic studies showing a pseudoaneurysm with or without stranding, periaortic fluid or air that was *not* thought to be an atherosclerotic penetrating aortic ulceration. Radioisotope tagged white blood cell scans were not routinely used as a diagnostic study given its lack of specificity [8]. Positron-emission tomography with computed tomography (PET-CT)

was *not* used in this study to confirm the presence of an infected graft or mycotic pseudoaneurysm. PET-CT may have a high positive and negative predictive value for graft infection and provides valuable information in the diagnosis of mycotic aneurysm [8,24-26]. Since the conclusion of this study, we have been using PET-CT when other clinical features were equivocal.

Patients were placed on broad spectrum or specific antibiotics according to the preoperative cultures obtained. The surgical principles of radical debridement of infected and devitalized tissue, foreign material and prosthetic graft were followed. Aortic reconstruction was performed using ascending/arch, descending aortic, aorto-iliac and femoral artery cryopreserved allograft (CryoLife, Inc., Kennesaw, GA; LifeNet Health, Virginia Beach, VA). To reconstruct the main body aorta, non-valved ascending and arch CPAs were sutured end-to-end to reconstitute the aorta. Occasionally, descending CPA was used for a smaller diameter descending or thoracoabdominal aortic reconstruction. The brachiocephalic branches of the CPA arch were used to attach brachiocephalic or visceral vessels. For thoracoabdominal aortic reconstruction, femoral artery and aorto-iliac CPAs were attached to the main body CPA to revascularize visceral arteries. In patients with aortic repair encompassing the aortic root, ascending aorta and transverse arch, 1.3±0.5 ascending/arch CPAs were used. In patients with descending or thoracoabdominal aortic repair, 1.9±1.0 CPAs were used. In extensive ascending, transverse arch and descending or thoracoabdominal aortic reconstruction, 3.3±1.3 CPAs were required.

For operations involving the descending or thoracoabdominal aorta with or without arch replacement, our technique has been described elsewhere using deep hypothermia and circulatory arrest [27-29]. Lumbar drains were not placed given the risk of epidural space infection. Motor evoked potentials (MEPs) and somatosensory evoked potentials were monitored intraoperatively. In the absence of placing lumbar

drains for spinal cord ischemia, if the MEPs were absent in the lower extremities, aggressive blood pressure elevation was initiated.

Teflon-felt pledgets, which have high risk for reinfection, were avoided. Self-made CPA tissue pledgets were used if the anastomoses required hemostatic sutures. Adhesive glues or hemostatic gels were not used to avoid placing foreign body in the infected surgical field.

Intraoperative cultures were taken to guide postoperative antimicrobial treatment. In the event that preoperative and intraoperative cultures were negative, broad spectrum antibiotics were administered. Intravenous antimicrobials were given for 6 weeks postoperatively. Long-term oral agents were administered on a case-by-case basis. Follow up CT angiograms were performed at 6 months, one year, and biannually thereafter. New pseudoaneurysm formation was interpreted as CPA suture line disruption and surgical reintervention was recommended.

Follow up was documented in the electronic medical record of our institution. Forty-three of 46 (93%) operative survivors had at least one follow up visit. Mean follow up was 36 ± 34 months. Median follow up was 25 months.

Statistical Analysis

The study is retrospective. Continuous variables are represented as the mean with standard deviation or median with interquartile range (IQR). Categorical variables are represented as the number and percentage of the cohort. Mortality was identified by the electronic medical record of Indiana University School of Medicine, the Indiana Health Information Exchange and the Social Security death index.

Kaplan-Meier estimates of survivor function and corresponding 95% confidence intervals were calculated and plotted. The statistical software package employed was R:A Language and Environment for Statistical Computing, R foundation for Statistical Computing, Vienna, Austria.

Results

The preoperative patient characteristics are included in Table 1. The mean age was 63 ± 14 years. Men comprised 64% of the cohort. Seventeen patents (34%) had mycotic aneurysm of the thoracic or thoracoabdominal aorta (Primary Mycotic group). Thirty-three (66%) patients had an infected thoracic or thoracoabdominal aortic graft (Infected Graft group). Preoperative bacteremia or fungemia was identified in 42% of patients. Other presenting symptoms that were ultimately related to an infected graft or mycotic aneurysm included hemoptysis (12%), gastrointestinal bleed (4%). Aortic rupture was the presenting event in 8%. Pseudoaneurysm was present on CT scan in 52%.

Prior open cardio-aortic operation was found in 37 patients and prior thoracic endovascular repair in 6. Prior operations are listed in Table 2. Surgical procedures and extent of aortic repair performed in the study are found in Table 3. The procedures performed included replacement of the aortic root, ascending aorta or transverse arch in 19, replacement of the descending or thoracoabdominal aorta in 27 and extensive replacement of the ascending, arch and descending or thoracoabdominal aorta in 4. In Table 3, the procedures performed are subdivided into Infected Graft and Primary Mycotic groups. There were differences in type or extent of procedures performed between the groups in regards to reoperations, aortic root replacement, replacement of the ascending aorta and hemiarch. These procedures occurred more often in the Infected Graft group.

An extent II thoracoabdominal aneurysm (TAAA) repair with CPA was not performed due to the difficulty, complexity and extreme duration of such a procedure. The one patient had infection localized to the thoracic portion of the aortic graft after extent II TAAA repair and had replacement of the descending aorta from native aortic tissue proximally to incorporated distal descending aortic graft. No attempt was made to remove all Dacron graft since the infection appeared to be localized to the descending aortic portion. One patient had thoracoabdominal aortic bypass to the abdominal visceral arteries using CPA. This patient had a pseudoaneurysm of the ligated infrarenal aortic stump after infrarenal graft excision and extraanatomic bypass. The entire abdominal aorta was resected to place the aortic suture line in the thorax. Aorto-iliac CPA was sutured end-to-end to the distal descending aorta and femoral artery CPA was sutured end-to-side to the aorto-iliac CPA to revascularize the visceral vessels individually with CPA limbs. In all other patients, the infected grafts were completely excised and replaced with in-situ CPA.

Positive preoperative cultures revealed a preponderance of staphylococcus, streptococcus and enterococcus. Intraoperative cultures showed a preponderance of gram positive cocci, fungi, gram negative and anaerobic species. Salmonella infection was uncommon (Tables 4 and 5). Methicillin-resistant staphylococcus aureus was present in 6 of 17 in the Primary Mycotic group and in only 1 of 33 in the Infected Graft group. Interestingly, preoperative cultures were the same as intraoperative cultures only in 18%. Additional or different organisms by intraoperative culture were found in 6%. Preoperative and intraoperative cultures were negative in 56% and 36%, respectively.

Operative results are found in Table 6. Operative mortality was 8%. Stroke occurred in 4%, spinal cord ischemia in 2%. Acute renal failure using the Society of Thoracic Surgeons definition was 20%. Three patients (6%) required renal replacement therapy. Respiratory failure occurred in 24% with 6% of

patients requiring tracheostomy. In Table 6, the operative outcomes are divided into the Infected Graft and Primary Mycotic groups. There were no differences in operative outcomes between the groups.

Reoperations and Operative Mortality

Eight patients required early reoperation. Four patients developed pseudoaneurysm of the CPA repair within 9 months. Three patients had reoperative repair where new CPA was used to repair the pseudoaneurysm. The original CPA was preserved when possible. Findings at reoperation revealed disruption of native tissue to CPA suture lines. The fourth pseudoaneurysm patient refused reoperation and eventually had emergent thoracic endograft repair after pseudoaneurysm rupture. The other patients who required reoperation had the following indications: 1) planned reoperation to remove descending followed by ascending aortic graft material, 2) persistent chylothorax, 3) postoperative hemothorax, and 4) development of an aorto-esophageal fistula with hemorrhage. Four patients had operative mortality caused by development of an aorto-esophageal fistula with hemorrhage (two patients, including the patient who had reoperation), a massive embolic stroke and multiorgan failure.

Blood product utilization for the hospital admission is shown in Table 7. Median packed red blood cell transfusion was 8 units, interquartile range 9.75. Fresh frozen plasma usage was median of 4 units, interquartile range 6. Included in Table 7 is a subgroup analysis of the Infected Graft and Primary Mycotic groups showing no difference in blood product utilization.

Survival analysis is shown by the method of Kaplan and Meier in Figure 1. Survival analysis includes operative deaths. Patients are censored after the last visit documented in the medical record. One, two and five year survival was 84%, 76% and 64%, respectively for all patients. Although not shown in the

figure, there was no difference in mid-term survival between the Infected Graft and Primary Mycotic groups.

Comment

The bulk of the surgical literature concerning mycotic aneurysm and infected aortic graft centers upon the abdominal aorta and iliac and femoral arteries where in-situ reconstruction or extraanatomic bypass are options. Unlike the abdominal aorta and peripheral vessels, there are few instances where extraanatomic bypass strategies are suitable for thoracic or thoracoabdominal aortic infection or infected graft. Therefore, different operative strategies have been proposed including in-situ reconstruction with rifampin soaked Dacron, Dacron with biological tissue coverage, bovine pericardium, and cryopreserved allograft [3,4,11,13,17-21,30-33].

Rifampin bonded Dacron with or without biological tissue coverage in abdominal aortic application can have reinfection rates of 22%, although others have reported reinfection rates of 0-4% on mid-term follow up [12,33-35]. Without exception, there is a need for lifetime suppressive antibiotics using prosthetic graft in an infected field [4,8]. Bovine pericardial sheets tailored to reconstruct the thoracic aorta are easily accessible and are easy to use, but this technique does not have extensive clinical experience or follow up [30].

The advantages of CPA in vascular reconstruction include its resistance to infection, extrapolation of known outcomes in aortic root reconstruction for endocarditis and favorable mid-term survival [8,13-17,23,36]. The processing of the CPA involves harvesting, disinfection and cryopreservation. Multiple broad spectrum antimicrobial agents are used to treat the vascular tissue which may confer resistance to infection. Additionally, the immunological reaction to the cells within the extracellular matrix of the

CPA may also confer infection-resistance [8,14,36]. No patients in our series developed reinfection or deterioration of the CPA greater than 9 months after the index operation. The 5 year survival among studies using CPA for aortic and arterial reconstruction is a commendable 50-60%, similar to our 5 year survival of 64% [17,18,23,37].

The disadvantages of CPA reconstruction include the lack of universal availability, fragility, expense, shape and length of the tissue, and need for early surveillance for pseudoaneurysm formation and allograft deterioration [18,21-23]. We have found, as have others, a risk of early failure of the CPA due to anastomotic pseudoaneurysm and fistula formation likely from exposure to ongoing infection [13,17,18,21,22,31,38]. Other mechanisms for early failure include anastomotic tension and subsequent breakdown, tissue friability and inadequate antimicrobial coverage [22].

In our series, early or ongoing exposure to infection resulted in rupture or pseudoaneurysm formation within 9 months in 10% of our patients. Upon reoperation, the defect in the repair was from deterioration of the CPA tissue at the suture lines. In particular, repair of aorto-esophageal fistula with primary esophageal repair, autologous tissue coverage and reconstruction of the aorta with CPA in our series (n=2) was fraught with complication: early hemorrhage leading to death and pseudoaneurysm leading to reoperation. Chiesa and colleagues also found that aorto-enteric fistulae in abdominal aortic graft infection are a risk factor for operative mortality using CPA [39]. As our experience with autologous tissue coverage *in addition to* CPA reconstruction has been limited to aorto-esophageal fistula repair, we cannot speculate upon the utility of these adjuncts to reduce the incidence of early pseudoaneurysm formation.

The duration of antibiotic coverage, in our institution, is typically 6 weeks after the source of an intravascular infection is surgically removed. We have given oral suppressive antibiotics on a case-by-case basis according to the virulence of the organism, fungal infection, presence of prosthetic graft or valve in other locations. Eight of 50 patients had long-term oral antimicrobial therapy. Although the infection-resistance of the CPA is superior to prosthetic graft, uncleared or inadequately treated infection may cause early graft failure [12,13,17,18,21,22,38]. It is reasonable to place *all* patients with infected aortic graft or native aorta with CPA reconstruction on 3 to 6 months of oral antibiotics after the intravenous course has been completed as has been suggested by the 2016 American Heart Association Scientific Statement [8,37]. We have changed our practice and have insisted upon at least 3 months of oral antimicrobial therapy after intravenous therapy has been completed.

Limitations of the study include those that are inherent to an observational, single-institution, retrospective study. The outcomes of the study may not be generalizable as the operations were performed at a tertiary care hospital by 2 surgeons (J.C. and J.F.). Follow up for operative survivors, although 93%, was not complete and the etiology of late mortality was often unknown. Late complication of the CPA repair may have been missed. As a result, our survival analysis has a number of censored patients. The assessment of operative candidacy was subjective, based on the surgeon's experience and clinical condition of the patient. Therefore, an unknown number of patients were not offered operative intervention and are not included as part of the study.

Given the advantages and despite the disadvantages, this study demonstrates that the use of in-situ cryopreserved allograft is a reasonable option for the treatment of infected thoracic and thoracoabdominal aortic grafts and mycotic aneurysms of the thoracic and thoracoabdominal aorta. Early pseudoaneurysm

formation may occur where local infection is not controlled and suture line disruption can result. In our cohort after 9 months, the CPA repair has remained intact and without pseudoaneurysm formation.

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Table 1. Patient Characteristics.

	n=50	%
Age (years)	62.9±13.9	
Male gender	32	(64)
Hypertension	38	(76)
Hyperlipidemia	29	(58)
Diabetes Mellitus	15	(30)
Coronary artery disease	24	(48)
Chronic kidney disease	9	(18)
Chronic obstructive pulmonary disease	13	(26)
Bacteremia/Fungemia	21	(42)
Hemoptysis	6	(12)
Gastrointestinal bleeding	2	(4)
Rupture	4	(8)
Pseudoaneurysm	26	(52)

Values represented are the mean ± standard deviation or number and percentage of the total cohort. Chronic kidney disease is defined as glomerular filtration rate < 60 mL/min/1/73m^2. Chronic obstructive pulmonary disease diagnosis is based upon spirometry, clinical signs and symptoms. Diabetes mellitus includes both insulin dependent and non-insulin dependent diabetes.

Table 2. Prior Operations of all patients.

	n=50	%
Root replacement/Bentall procedure	6	(12)
Aortic valve replacement	4	(8)
Ross procedure	3	(6)
Ascending replacement	21	(42)
Hemiarch replacement	10	(20)
Total arch replacement	2	(4)
Extent I TAAA	5	(10)
Extent II TAAA	1	(2)
Extent IV TAAA	1	(2)
Open AAA repair	2	(4)
TEVAR	6	(12)

Values represented are the number and percentage of the cohort.
TAAA=thoracoabdominal aneurysm repair, AAA=abdominal aortic aneurysm repair, TEVAR=thoracic endovascular aortic repair

Table 3. Operations Performed with CPA.

	All patients		Infected Graft		Primary Mycotic	
	n=50	%	n=33	%	n=17	%
Reoperative procedure	37	(74)	33	(100)	4	(24)*
Root replacement/Bentall procedure	10	(20)	10	(30)	0	(0)*
Aortic valve replacement	1	(2)	1	(3)	0	(0)
Ascending replacement	22	(44)	20	(61)	2	(12)*
Hemiarch replacement	13	(26)	13	(39)	0	(0)*
Total arch replacement	9	(18)	7	(21)	2	(12)
Descending replacement	17	(34)	9	(27)	8	(47)
Extent I TAAA	8	(16)	3	(9)	5	(29)
Extent III TAAA	1	(2)	0	(0)	1	(6)
Extent IV TAAA	4	(8)	2	(6)	2	(12)
Thoracoabdominal bypass	1	(2)	1	(3)	0	(0)

Values represented are the number and percentage of the cohort. TAAA=thoracoabdominal aneurysm repair. Significant statistical differences between the Infected Graft group and the Primary Mycotic group are represented by (*).

Table 4. Preoperative culture results.

	n=50	%
Staphylococcus	12	(24)
Streptococcus	3	(6)
Salmonella	2	(4)
Enterococcus	2	(4)
Clostridium	1	(2)
Enterobacter	1	(2)
Kocuria	1	(2)
Candida	2	(4)
Penicilium	1	(2)
Negative	28	(56)

Values represented are the number and percentage of the cohort. Percentages do not add to 100% as some cultures had polymicrobial results.

Table 5. Intraoperative culture results.

	n=50	%
Staphylococcus	12	(24)
Enterococcus	6	(12)
E. Coli	3	(6)
Pseudomonas	2	(4)
Corynebacterium	2	(4)
Peptostreptococcus	2	(4)
Streptococcus	2	(4)
Salmonella	1	(2)
Clostridium	1	(2)
Enterobacter	1	(2)
H. Flu	1	(2)
Klebseilla	1	(2)
Fusobacterium	1	(2)
Candida	3	(6)
Scopulaiopsis	1	(2)
Negative	18	(36)

Values represented are the number and percentage of the cohort. Percentages do not add to 100% as some cultures had polymicrobial results.

Table 6. Operative Results.

	All patients		Infected Graft		Primary Mycotic	
	n=50	%	n=33	%	n=17	%
Operative mortality	4	(8)	3	(9)	1	(6)
Stroke	2	(4)	2	(6)	0	(0)
Paralysis	1	(2)	1	(3)	0	(0)
Acute renal failure	10	(20)	8	(24)	2	(12)
Any hemodialysis	3	(6)	2	(6)	1	(6)
Respiratory failure	12	(24)	10	(30)	2	(12)
Tracheostomy	3	(6)	2	(6)	1	(6)
Postop atrial fibrillation	3	(6)	0	(0)	3	(18)
Reoperation	8	(16)	4	(12)	4	(24)

Values represented are the number and percentage of the cohort. There are no statistical differences between the Infected Graft group and the Primary Mycotic group.

Table 7. Blood product utilization.

	All patients n=50		Infected Graft n=33		Primary Mycotic n=17	
	Median	IQR	Median	IQR	Median	IQR
PRBC (unit)	8	9.75	8	10	6	4
FFP (unit)	4	6	4	4	2	4
Cryo (10 pack)	1	2	1	1	0	1
Platelet (pheresis)	2	1	2	2	1	2

Values represented are median and interquartile range. There are no statistical differences between the Infected Graft group and the Primary Mycotic group.

Figure Legend

Figure 1. Kaplan-Meier Survival Analysis for all patients with 95% confidence intervals. Time is delineated in months. The number at risk is associated with each time point.